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**UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
OAKLAND DIVISION**

JONNIE HOMYK, et al.,

Plaintiffs,

v.

CHEMOCENTRYX, INC. et al.,

Defendants.

Master File No. 4:21-cv-03343-JST and
related case, No. 4:21-cv-04357

**LEAD PLAINTIFF'S OPPOSITION
TO DEFENDANTS' CROSS-MOTION
FOR SUMMARY JUDGMENT AND
LEAD PLAINTIFF'S REPLY IN
SUPPORT OF MOTION FOR
PARTIAL SUMMARY JUDGMENT**

Hearing Date: July 31, 2025
Time: 2:00 p.m.
Judge: Honorable Jon S. Tigar

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TABLE OF TERMS AND ABBREVIATIONS

Term	Definition
AAV	ANCA-Associated Vasculitis
AC	Amended Consolidated Class Action Complaint for Violations of Federal Securities Laws, ECF No. 47. The alleged false and misleading statements referenced in the Amended Complaint are contained in Exhibits 1 to 37 of the Uslaner Declaration (ECF No. 268)
AC Charter	ADVOCATE Adjudication Committee Charter
AdCom	FDA's Arthritis Advisory Committee
AdCom Meeting	May 6, 2021 meeting of the FDA's Arthritis Advisory Committee
ADVOCATE	The "Avacopan Development in Vasculitis to Obtain Corticosteroid Elimination and Therapeutic Efficacy" trial
ADVOCATE Press Release	ChemoCentryx press release, issued after the close of trading on November 25, 2019, that purported to announce the results of the ADVOCATE
ANCA	Anti-Neutrophil Cytoplasmic Autoantibody
Briefing Book	FDA's briefing book for the AdCom Meeting, published online on May 4, 2021, which is Exhibit 126
BVAS 3	Birmingham Vasculitis Activity Score version 3
CC Order	Order Granting Motion to Certify Class, ECF No. 131
ChemoCentryx	ChemoCentryx, Inc. or CCXI
Class Period	November 26, 2019 and May 6, 2021, inclusive
CMO	ChemoCentryx's Chief Medical Officer
<i>Daubert</i> Order	Order Resolving Motions to Exclude, ECF No. 289
DILI	Drug-induced-liver-injury
DMC	ADVOCATE Data Monitoring Committee
Dr. Bekker	Dr. Pirow Bekker, ChemoCentryx's former CMO
Dr. Bonder	Dr. Alan Bonder, a practicing hepatologist and an expert on issues concerning, among other things, hepatology and DILI. Dr. Bonder submitted expert reports in this matter, which are Exhibits 152 and 153
Dr. Cain	Dr. Matthew D. Cain, an expert on issues concerning, among other things, loss causation and damages. Dr. Cain submitted expert reports in this matter, which are Exhibits 148 and 149
Dr. Glassock	Dr. Richard Glassock, member of the DMC
Dr. Goodkin	Dr. David Goodkin, chair of the DMC
Dr. Helfgott	Dr. Simon Helfgott, a practicing rheumatologist and an expert on issues concerning, among other things, treating patients with AAV and evaluating and conducting clinical studies. Dr. Helfgott submitted expert reports in this matter, which are Exhibits 154 and 155
Dr. Hillson	Dr. Janet Hillson, ChemoCentryx's former CMO
Dr. Jayne	Dr. David Jayne, a principal investigator of the ADVOCATE and co-Chair of the Adjudication Committee
Dr. Kanagala	Dr. Suhasini Kanagala, ChemoCentryx's Director of Global Regulatory Affairs
Dr. Kelleher	Dr. Catherine Kelleher, former CMO
Dr. Maddrey	Willis Maddrey, M.D, a liver expert retained by ChemoCentryx

Term	Definition
Dr. Madigan	Dr. David Madigan, an expert on issues concerning, among other things, biostatistics, pharmacovigilance, and the statistical evaluation of clinical studies. Dr. Helfgott submitted expert reports in this matter, which are Exhibits 156 and 157
Dr. Merkel	Dr. Peter A. Merkel, a principal investigator of the ADVOCATE and member of the Adjudication Committee
Dr. Walton	Dr. Marc Walton, an expert on issues concerning, among other things, drug development and approval, clinical trial design, and the NDA review process. Dr. Walton submitted expert reports in this matter, which are Exhibits 150 and 151
Dr. Wang	Dr. Chao Wang, member of the DMC
Dr. Yue	Dr. Huibin Yue, ChemoCentryx's VP of Biometrics
DX	Refers to exhibits attached to the declaration of Meryn Grant in support of Defendants' motion for summary judgment, ECF No. 282
Ex.	Refers to exhibits to the Uslaner Decl. (ECF No. 268) accompanied by Exs. 1-37 or the Uslaner Decl. (filed herewith) accompanied by Exs. 38-183
FDA	Food and Drug Administration
FINRA	Financial Industry Regulatory Authority
Glucocorticoids	A class of steroids
Hy's law	Rule used by doctors to determine whether a patient is at high risk of liver failure due to a particular drug
Mot.	Defendants' Notice of Motion and Cross-Motion for Summary Judgment and Opposition to Lead Plaintiff's Motion for Summary Judgment, ECF No. 279
MTD Order	Order re: Defendants' Motion to Dismiss, ECF No. 61
NDA	New Drug Application
<i>NEJM</i>	<i>New England Journal of Medicine</i>
Prednisone	A steroid medication
SAP	Statistical Analysis Plan for the ADVOCATE
TMF	Trial master file kept on-site by drug manufacturer and not submitted with NDA

I. INTRODUCTION

Defendants’ motion for summary judgment should be denied. In their motion, Defendants urge the Court to overrule its prior orders, disregard Ninth Circuit law, and ignore the evidence.

Below are just some of the facts that preclude summary judgment for Defendants:

- At the same time Schall touted ADVOCATE’s “safety results” (sending ChemoCentryx’s stock price soaring), Defendants knew—because they were repeatedly told by a unanimous DMC and their expert hepatologist, Dr. Maddrey—that ADVOCATE showed avacopan causes serious liver damage. Exs. 38-60; 160-162.¹ Schall never disclosed these facts to investors, concealing Dr. Maddrey’s hepatotoxicity report even from the FDA.
- The DMC repeatedly told Defendants that their public statements, including in the ADVOCATE Press Release and the *NEJM*, were false and misleading. Exs. 38-45. The DMC urged Schall to issue retractions and to send their unanimous letters to the FDA. Schall did neither and, even more, told the Company’s CMO—who also pressed for disclosure—that she was “too vocal” and needed to “stop talking” about liver toxicity. Ex. 65 at 54:4-57:5.
- The Chair of the DMC warned Defendants that avacopan’s liver toxicity was “material information” that, absent disclosure to investors, put its executives “at a huge risk of being accused of insider trading.” Exs. 165 at 270:19-272:15. Schall and his right-hand man, Dr. Bekker, ignored these warnings, instead unloading over \$40 million of their personal shares.
- The FDA raised serious concerns about ADVOCATE, including that it was “likely not adequate to support [Defendants’] safety comparisons” and that it was not clear that “replacing potential toxicity of treatment with [steroids] with potential toxicities with avacopan represents a clinical benefit to patients.” Exs. 66-70; 72-77. Defendants disclosed none of this, including that they intentionally undertreated patients to manufacture a “superiority” finding. Exs. 107-111.

Rehashing the same arguments they have tried (and failed) throughout over three years of litigation, Defendants ask the Court to ignore the evidence against them because the FDA “agreed” with ADVOCATE’s design. Not so. As ChemoCentryx’s Director of Regulatory Affairs admitted in one damning email, the FDA ***“disagree[d] with the study design and the endpoints,” but “we went ahead with the same study design.”*** Ex. 66. Nor did the FDA ever “approve” Defendants’ claims about avacopan after the Class Period. To the contrary, the FDA concluded that avacopan “does ***not*** eliminate glucocorticoid use” and should only be used ***“in combination with”*** standard therapy, with ***“serious cases of hepatic injury”*** in ADVOCATE. Ex. 71. What’s more, the FDA would not have “approved” avacopan ***at all*** had ChemoCentryx not manipulated the trial data—reviewing the data on an unblinded basis and changing patients from “non-responders” to

¹ Unless otherwise noted, internal quotation marks, alterations, and citations are omitted, and emphasis is added.

1 “responders”—to flip a missed “superiority” result at the end of the trial. Exs. 107-117.

2 Defendants’ arguments also ignore on-point Ninth Circuit law that once defendants “tout
3 positive information to the market” about a clinical trial, “‘they [are] bound to do so in a manner
4 that wouldn’t mislead investors,’ including disclosing adverse information that cuts against the
5 positive information.” *Schueneman v. Arena Pharms., Inc.*, 840 F.3d 698, 706 (9th Cir. 2016).
6 This rule does not change if the drug is “approved” after the Class Period. *Id.* at 703.

7 Defendants’ hodge-podge of other arguments fares no better. The Court has already found,
8 multiple times, that the “truth” was never disclosed to investors before the FDA’s Briefing Book
9 and AdCom Meeting. *See* CC Order at 8-12; *Daubert* Order at 33-36. The Court has also already
10 rejected Defendants’ arguments that their misrepresentations should be excused because they were
11 “forward-looking” or “puffery.” MTD Order at 25-29. Nor is there any merit to their contentions
12 that the ADVOCATE Press Release, issued after market-hours on November 25, 2019, is an
13 “inactionable pre-class period statement” or that Counsel “disclaimed” any liability theories.
14 Defendants are not entitled to summary judgment, and disputed facts should be resolved by a jury.

15 II. SUMMARY OF FACTS

16 This case arises from misleading statements made by ChemoCentryx and Defendant Schall
17 about ADVOCATE, the Company’s key clinical trial for avacopan and the basis for its NDA to
18 the FDA. The results of ADVOCATE were essential to ChemoCentryx’s ability to raise the capital
19 it needed to survive, as it had no drugs on the market, generated no sales revenue, and operated at
20 a significant loss. Ex. 148 ¶¶23, 48. Defendants told investors that ADVOCATE showed avacopan
21 was a far safer replacement for steroid-based therapy, and analysts “predicated” their
22 recommendations to buy their stock on it. Exs. 72; 148 ¶¶64-69.

23 When the truth was revealed—including that the FDA had warned Defendants for years
24 about grave deficiencies in ADVOCATE and its results—ChemoCentryx’s stock price plummeted
25 by nearly **80%**. Ex. 148 ¶105, Ex. 3. While investors suffered immensely, Defendants profited:
26 Defendant Schall reaped **\$40 million** through insider stock sales, and the Company secured **\$325**
27 **million** through its largest stock offering ever. Exs. 118; 144.

A. Defendants Misled Investors About ADVOCATE’s Safety Results

Throughout the Class Period, Defendants told investors that ADVOCATE demonstrated avacopan’s supposed core commercial advantage: it was far safer than competing therapies. AC ¶¶217-90; Exs. 1-37. They touted how it “had fewer adverse events and fewer serious adverse events” in ADVOCATE, a “very acceptable safety profile”; that ADVOCATE provided “irrefutable” and “definitive evidence statistically that [avacopan] was superior in reducing glucocorticoid-related toxicities using a newly-validated glucocorticoid toxicity index”; and that “validated quality of life metrics also statistically improved for” patients taking avacopan. *Id.*

Defendants’ statements were false and misleading. In truth, ADVOCATE showed that avacopan caused: (i) drug-induced liver injury (“DILI”), confirmed by positive de-challenges and re-challenges, which is the “gold standard” in proving causality; (ii) cases of “Hy’s Law”; (iii) *six-times* more hepatobiliary serious adverse events than alternative treatment; and (iv) *seven-times* more study discontinuations due to liver injury.²

These facts were told to Defendants, including by the DMC for ADVOCATE—a panel of six prominent scientists tasked with overseeing, analyzing, and advising the Company on avacopan’s safety. Exs. 38, 45-52; 165 at 72:15-23, 91:3-7, 146:2-148:13, 182:11-16; 163 at 42:22-24, 155:10-25, 183:8-184:8, 185:23-186:3. For instance, on June 6, 2018, Schall received a unanimous DMC letter stating that they were “concerned about [avacopan’s] hepatotoxicity,” adding that “[i]t is remarkable to observe cases of marked drug-induced liver injury this early in a new drug’s development.” Ex. 38. The ADVOCATE trial provided “gold standard” evidence of “potentially fatal risks of...hepatotoxicity associated with [avacopan].” Exs. 51-52; *see also* Exs. 49-50; 52; 101-102; 163 at 183:8-184:13, 209:24-212:13; 165 at 72:8-23, 198:20-199:23.

In July 2018, at the DMC’s insistence, ChemoCentryx retained Dr. Maddrey, a world-renowned hepatology expert. Exs. 56; 171 at 33:9-24; 165 at 184:1-19; 163 at 153:10-15. He agreed with the DMC, testifying that “[e]very time I had a communication with ChemoCentryx it

² Exs. 152 ¶¶25-76; 156 ¶¶35, 37; *see also* Exs. 41; 47; 49; 51; 53; 57; 59; 124; 125; 172; 65 at 102:13-17, 144:17-147:15, 159:15-160:1, 167:13-169:9; 163 at 109:16-110:8, 128:11-129:25, 139:22-140:1, 190:7-191:12; 165 at 66:11-20, 85:4-87:24, 146:7-24, 214:15-217:2, 239:5-240:4; 169 at 50:7-52:15, 75:12-21; 170 at 134:6-17, 205:23-207:4; 171 at 184:23-186:14; 173 at 65:4-67:12, 68:13-70:21.

1 was that I had ongoing concerns [about avacopan’s] liver toxicity.” Exs. 169 at 167:12-19, 143:3-
 2 19, 159:23-161:5, 326:15-328:22, 355:11-356:3; 41; 51; 57-60. He told Defendants that there were
 3 “clear instances of serious drug induced liver injury and will be FDA concerns.” Ex. 57. He sent
 4 Defendants a written report—which Schall falsely testified he never received—documenting cases
 5 of DILI, de-challenges, re-challenges, Hy’s law, and overall “troubling safety signal.” Exs. 169 at
 6 239:21-242:6; 59; 164 at 90:9-12.

7 The DMC also specifically told Defendants that their public statements misleadingly
 8 “*downplay[ed] potential drug toxicities*” associated with avacopan. Ex. 41; *see also* Exs. 38-40;
 9 42-44; 165 at 260:19-261:9, 265:17-267:1, 270:19-272:15, 299:6-300:2, 354:8-355:2, 359:18-
 10 360:7; 163 at 235:21-240:9, 267:21-270:3, 277:14-278:2, 279:20-280:7. In an email sent to Schall,
 11 Dr. Glassock criticized the ADVOCATE Press Release for saying “very little about hepato-
 12 toxicity and other -related side effects which bothered us a great deal.” Ex. 43. He explained that
 13 the press release “*doesn’t fairly present the safety risks observed [on avacopan].*” Ex. 163 at
 14 235:21-240:9. Dr. Goodkin agreed with Dr. Glassock: the ADVOCATE Press Release
 15 “substantially understated the safety risks associated with avacopan,” was “really unbalanced,”
 16 and “there’s no way in the world” readers would realize based on it that there were “any kind of
 17 worries” about avacopan’s safety. Ex. 165 at 260:19-261:9, 265:17-267:1. Dr. Maddrey also
 18 concurred, adding that the ADVOCATE Press Release “substantially understate[d] the safety risks
 19 observed.” Ex. 169 at 355:3-356:3; 335:20-342:17.

20 Even more, Dr. Goodkin repeatedly told Defendants that avacopan’s undisclosed liver
 21 toxicity was “*material information*” that, absent disclosure to investors, put ChemoCentryx’s
 22 executives “*at a huge risk of being accused of insider trading.*” Exs. 165 at 270:19-272:15; 42.

23 The DMC also specifically told Defendants that their article about ADVOCATE in the
 24 *NEJM* was misleading. Exs. 38-40; 165 at 299:6-300:2, 354:8-355:2, 359:18-360:7; 163 at 267:21-
 25 270:3, 277:14-278:2, 279:20-280:7. The *NEJM* article was “not a fair statement of the actual
 26 conduct of the trial” and gave a “misimpression that there was no safety signal on avacopan.” Ex.
 27 163 at 277:14-278:2, 279:20-280:7. In a series of unanimous letters sent directly to Schall, the
 28 DMC implored Schall to “[i]mmediately submit a letter to the editor of the [*NEJM*] clarifying the

1 hepatotoxicity risks,” and to immediately send their letter to the FDA. Ex. 38; *see also* Exs. 39-40.
 2 Schall did neither. Ex. 62; 163 at 289:2-6; 164 at 26:10-24, 31:23-32:8.

3 ChemoCentryx executives agreed with the DMC’s concerns. Dr. Kelleher, its CMO,
 4 directly raised to Schall her “concerns about the liver safety signal,” urging him to change how
 5 they “present the liver data in his communications externally.” Ex. 65 at 54:4-57:5. Disclosures
 6 were necessary because “there was a difference in liver [toxicity] between the treatment arm of
 7 ADVOCATE and the placebo arm,” with Kelleher telling Schall to “call out certain cases” of liver
 8 damage. Exs. 65 at 54:4-57:5, 246:20-250:16; 64 at 641. In response, Schall told her she was “too
 9 vocal,” and to “stop talking” about the liver safety signal. Ex. 65 at 54:4-57:5. Schall also precluded
 10 her from communicating via email—telling her “*no safety info in email*” (unless she was *denying*
 11 that there were any Hy’s law cases) and warning that “[n]ot adhering to [this policy] will be
 12 considered by me as a grievous deficiency in performance.” Exs. 78-80. Schall admitted that he
 13 “understood that emails are produced in litigation.” Ex. 164 at 293:13-15.

14 **B. Defendants Misled Investors About ADVOCATE’s Primary Endpoints**

15 Throughout the Class Period, Defendants also misled investors by touting ADVOCATE’s
 16 “efficacy” results, claiming avacopan satisfied both primary endpoints: “non-inferiority” at week-
 17 26 and “superiority” at week-52, as compared to “standard of care.” AC ¶¶291-350; Exs. 1-37.

18 *First*, unknown to investors at the time, the FDA disagreed with ADVOCATE’s design.
 19 As Dr. Kanagala admitted in a September 2018 email, the FDA “*disagree[d]* with the study design
 20 and the endpoints...and we went ahead with the same study design.” Ex. 66. Dr. Walton reviewed
 21 the record in this case and concurs: the FDA consistently disagreed with ADVOCATE’s design,
 22 and repeatedly told this to ChemoCentryx. Ex. 150 ¶¶32-44; 66-70.

23 *Second*, also unknown to investors, the FDA specifically told Defendants that it “will *not*
 24 accept [ADVOCATE’s week-26] non-inferiority outcome as a primary endpoint.” Exs. 74; 66 at
 25 846; 69; 73. The FDA chastised Defendants for publicly stating otherwise, telling Defendants:
 26 “[W]e do not agree with your statements [in the SAP] which indicate that you will conclude to
 27 have a successful study” based on it. Ex. 67 at 029. Schall and Bekker knew the truth, confiding
 28 in each other that the “likelihood of FDA accepting a NI [non-inferiority] endpoint is 0.” Ex. 75.

1 **Third**, also unknown to investors, ADVOCATE did not “demonstrate[] avacopan's
 2 superiority over *standard of care*.” Ex. 5 at 18. Since the 1990s, standard of care has always
 3 included “maintenance therapy”; yet, in ADVOCATE, two-thirds of the patients were not given
 4 *any* maintenance therapy. Exs. 174 at 71:11-22; 170 at 350:14-351:18, 352:16-353:7; 81-85.
 5 Worse yet, ChemoCentryx intentionally undertreated patients because, as Defendants privately
 6 admitted, providing *actual* standard of care “would largely abolish relapses in this trial,”
 7 precluding avacopan from showing “superiority.” Exs. 87; 86; 88-91; 163 at 256:2-257:13.

8 Not only were investors kept in the dark about the true reasons why ChemoCentryx
 9 undertreated patients, they were also not told that the trial failed to achieve “superiority” when
 10 considering the patients who *actually* received standard of care. Exs. 84; 155 ¶¶91-98. Nor did
 11 investors know that the FDA had specifically told Defendants that this undertreatment of patients
 12 undermines “the clinical relevance of the [study’s] results,” “confound[ing] the results and
 13 bias[ing] the assessment of efficacy at Week 52.” Exs. 68, 70.

14 **Fourth**, also unknown to investors, Defendants violated ADVOCATE’s protocol
 15 requirement to use “BVAS version 3.” Ex. 112 at 429. Defendants knew this also. As Dr. Merkel
 16 told ChemoCentryx, they “*Can’t really call this BVAS 3,*” to which Bekker agreed, but replied “*I*
 17 *am not sure we should publicize [this fact] widely.*” Ex. 98. Defendants also knew that *if*
 18 ChemoCentryx had followed BVAS 3—including cases of persistent vasculitis—the study would
 19 have failed to demonstrate “superiority.” Exs. 149 at ¶¶77; 100.

20 **Fifth**, while Defendants touted their “relapse” analysis to investors, the FDA had already
 21 “reiterated” to Defendants that their relapse analysis would *not* be considered by the FDA at all
 22 because it was “problematic from a statistical point of view,” with “comparisons between non-
 23 randomized groups.” Exs. 66; 73; 155 at ¶¶82-83.

24 **C. Defendants Misled Investors About Steroid Use In The Avacopan Arm**

25 During the Class Period, Defendants also told investors that the avacopan arm of
 26 ADVOCATE “eliminated prednisone” (i.e., steroids), with Schall stating that ADVOCATE
 27 “resoundingly” showed “that steroids need not be used when avacopan is available,” stressing “*we*
 28 *simply took the steroids out of the mix.*” AC ¶¶351-404; Exs. 1-37. In reality, however, over 63%

1 of avacopan patients in ADVOCATE relied on “non-study supplied steroids” *to treat their*
 2 *vasculitis*. Exs. 95-97; 67 at 073. What’s more, steroid use for the purpose of treating vasculitis
 3 was no different between the “avacopan” and “standard of care” arms of the trial. Ex. 96.

4 Defendants knew these very facts. The DMC told Defendants that “avacopan” patients
 5 were receiving significant steroid treatment to treat their vasculitis, which “will confound
 6 comparisons.” Exs. 48; 93. The DMC further “warned [ChemoCentryx] on several occasions,
 7 ‘Hey, listen, the avacopan...patients are getting a lot [of] daily steroid. That is a concern. It...could
 8 artificially make it look like the avacopan is doing better than it should just from avacopan alone
 9 because *they’re getting bailed out with steroid.*’” Exs. 165 at 226:8-228:4; 163 at 313:16-21. The
 10 FDA, likewise, warned “that patients in [ADVOCATE] received steroids outside of the protocol
 11 specified steroid taper ... because of worsening of disease,” which undermined the study. Ex. 94.

12 **D. Defendants Misled Investors About ADVOCATE’s Secondary Endpoints**

13 To bolster their “safety” claims, Defendants also touted to investors the results from the
 14 trial’s “validated” secondary endpoints, which purportedly were “definitive evidence statistically
 15 that [avacopan was] superior in reducing glucocorticoid-related toxicities.” AC ¶¶218-90.

16 In reality, the FDA had consistently told Defendants these endpoints were *not* “validated,”
 17 “*not* adequate to support [their] safety comparisons,” and suffered statistical flaws undermining
 18 their “interpretability.” Exs. 66-67; 70; 72; 74; 154 at ¶¶59-64; 151 ¶¶86-101. Defendants privately
 19 agreed they were “*not* validated.” Exs. 101-105. Further, ChemoCentryx *admitted* that the FDA
 20 “*rightfully* pointed out that *none* of the secondary endpoints are acceptable from a Regulatory or
 21 labeling perspective.” Exs. 77; 66 at 845-46. Yet Defendants continued to tout the results of these
 22 “validated” secondary endpoints to investors—never once disclosing the truth.

23 **E. Defendants Misled Investors About Their Interactions with the FDA**

24 Defendants further assured investors during the Class Period that the “FDA [had] not
 25 highlighted any particular issues that would have to be discussed at [an] AdCom” and “the
 26 regulatory path is clear.” AC ¶¶407-08, 425-28; Exs. 10 at 824; 31 at 559. In truth, the FDA had
 27 told ChemoCentryx repeatedly and for years that: (i) the rampant use of non-study supplied
 28 steroids to treat vasculitis in the avacopan arm of the study and the failure to provide standard of

care “confound[ed] the results and bias[ed] the assessment of efficacy at Week 52” (Exs. 70; 66; 94); (ii) ChemoCentryx’s relapse analysis was “problematic from a statistical point” and, at most, “exploratory” (Ex. 66); (iii) the “FDA will not accept a non-inferiority outcome as a primary endpoint” (Exs. 66; 67 at 029); (iv) “none of the secondary endpoints are acceptable from a Regulatory or labeling perspective” (Exs. 77; 66-67); and (v) the trial had “not demonstrated significant improvement in safety or effectiveness” (Ex. 76 at 194).

F. Defendants Hid And Manipulated Trial Data And Adverse Reports

Determined to publicly report favorable results at all costs and boost ChemoCentryx’s stock, Defendants hid adverse reports from the FDA and DMC. Among other things:

- Defendants *never* provided Dr. Maddrey’s report to the FDA—even though the FDA specifically requires that “[r]eports of external consultant opinions solicited by the applicant should be provided to the FDA.” Exs. 164 at 92:21-93:2; 172 at -028. They also *never* provided Dr. Maddrey’s report to the DMC—a failure that constituted a “bad breach.” Exs. 50; 169 at 40:4-42:11.
- Defendants also *never* provided the FDA with the DMC’s correspondence and minutes, despite the DMC’s repeated and strongly worded insistence that they “do the right thing,” immediately provide these materials to the FDA, and not bury them in a TMF. Exs. 38-40; 61-63; 164 at 26:10-16, 31:23-32:8.
- Defendant Schall also lied to the DMC, falsely telling it that he informed Drs. Jayne and Merkel of the DMC’s concerns, as well as their request to speak with them. Exs. 39; 138; 174 at 27:9-28:18; 175 at 24:1-7, 36:24-38:20.

Worse yet, Defendants manipulated ADVOCATE’s data to falsely represent that it met its 52-week endpoint. In a private text message, Schall instructed Dr. Bekker to call him immediately after database-lock if the unblinded results of ADVOCATE showed that the study failed—all in violation of the Protocol. Exs. 107; 164 at 476:23-477:7. On November 8, 2019, after quality control measures were completed and the database was “locked,” Dr. Bekker and his colleagues learned that the study failed to show week-52 superiority. Exs. 124; 156 ¶¶66-67. Rather than admit these facts, Dr. Bekker instructed Dr. Yue to review the data, stating, “*We cannot afford to miss a superiority outcome here,*” but “[t]here were *no* discrepancies” found. Exs. 108-110; 176 at 181:5-182:20; 173 at 92:6-93:25. Bekker then reviewed the unblinded data and “found” five patients to flip—*all* from failure to success and *all* from the avacopan arm. Exs. 111, 177; 142 at 162:11-163:19. This unblinded data review and manipulation contravened both ADVOCATE’s

1 protocol, which stated that all cases must be adjudicated “*before* data finalization and unblinding”
2 (Ex. 112 at 492), and the AC Charter, which stated “[a]t the time of database lock, all the 52-week
3 BVAS data entered by the sites will be 100% source verified and cleaned...and *no changes* may
4 be [made] after data base lock” (Ex. 113 at 176). Bekker successfully compelled Dr. Jayne to
5 switch the five avacopan patients to “responders,” even though these patients were deemed “non-
6 responders” based on rules developed by Dr. Jayne and ChemoCentryx’s CMO to “address the
7 subjectivity” and “impose a strict control” on the primary endpoint determination. Exs. 114; 174
8 at 156:5-157:2. Defendants’ data manipulation was not driven by science: it was unjustified, as
9 confirmed by experts in the field. Exs. 156 ¶71; 157 ¶16; 155 ¶110; 163 at 317:2-319:5, 339:13-
10 340:4. The changes were also not driven by chance: the likelihood of Bekker identifying by chance
11 *only* patents in the avacopan arm and *only* switches from “non-responder” to “responder” is less
12 than 3%. Exs. 156 n. 85; 163 at 341:9-21.

13 Defendants actively concealed their ADVOCATE data manipulation from the regulators.
14 When FINRA asked when Drs. Bekker and Yue were first unblinded, Defendants falsely stated
15 “November 20, 2019.” Exs. 115; 178 at 222:15-224:22. When the FDA inquired about “unblinding
16 dates,” Defendants never mentioned a word about the November 8 unblinding. Exs. 116-117.

17 **G. Defendants Took Advantage Of ChemoCentryx’s Inflated Stock Price**

18 Defendants’ Class Period misstatements and omissions sent ChemoCentryx’s stock price
19 climbing, with an increase of *more than 700%* during the Class Period. Ex. 148 at Ex. 4.

20 Defendants took advantage of the Company’s increased stock price to line their own
21 pockets, despite Dr. Goodkin’s warnings that selling their shares—without disclosing the truth—
22 violated the federal securities laws. Exs. 42; 165 at 270:19-272:15. Just hours after they issued the
23 false and misleading ADVOCATE Press Release, Schall and Bekker unloaded \$15 million of their
24 personal shares, with Schall continuing his selling spree thereafter. Exs. 119; 118-A; 158.

25 Defendants also capitalized on the investor enthusiasm driven by their misleading
26 statements by conducting a massive, \$325 million stock offering, which was four-times larger than
27 any prior capital raise in the Company’s history. Ex. 144. This offering provided an infusion of
28 necessary capital, ensuring Schall would continue receiving executive compensation.

1 Defendants even tried to sell the Company altogether before the truth came out. In April
2 2020, ChemoCentryx shopped the Company to potential acquirers. Ex. 120. When these potential
3 acquirers asked questions, Schall lied to them, just as he did to investors. He told them that no
4 hepatotoxicity “causality assessment” had been performed—when, in truth, Dr. Maddrey had
5 performed this very analysis. Exs. 57; 59; 121. Potential acquirers noted that Schall acted like a
6 “talk show host” during meetings, obfuscating the true facts ultimately revealed. Exs. 122-123.

7 **H. The Truth Is Revealed**

8 Investors and the public began to learn the truth. On May 4, 2021, the FDA published the
9 Briefing Book in advance of the AdCom Meeting. The Briefing Book repeated, nearly verbatim,
10 many of the issues that the FDA, DMC, Dr. Maddrey, and others had privately communicated to
11 ChemoCentryx for years. Exs. 181; 149 ¶¶39; 153 ¶¶10. As Dr. Glassock testified, “the DMC
12 repeatedly warn[ed] ChemoCentryx about many of the same problems in ADVOCATE and its
13 results that the FDA highlighted in the briefing book.” Exs. 163 at 312:16-20; 93. And the Briefing
14 Book itself noted that, “during the avacopan clinical development, including the phase 3 design
15 stages, the Agency communicated *many of the [same] concerns*” to Defendants. Ex. 126 at 279.

16 Following the Briefing Book’s release, ChemoCentryx’s stock price plummeted by more
17 than **45%** in a single day. Ex. 148 ¶¶105. To stem the tide, Defendants went on a media blitz, urging
18 analysts and investors to ignore the Briefing Book and to await the AdCom Meeting just two days
19 later—where the FDA and AdCom experts would speak publicly. Exs. 148 ¶¶116-132; 130-132.

20 On May 6, 2021, the FDA convened its AdCom Meeting. Investors learned new facts about
21 ADVOCATE, as well as the significance of the FDA’s statements in the Briefing Book. Exs. 133
22 at 068-69, 157-58, 177, 185-86; 148 ¶¶137-144. While these facts were new to investors, they
23 were *not* new to ChemoCentryx. As Dr. Maddrey testified, he “told ChemoCentryx [in 2018 and
24 2019] what [the FDA’s liver expert was] saying here at the advisory committee meeting.” Ex. 169
25 at 328:18-22. Immediately following the AdCom Meeting, ChemoCentryx’s common stock
26 plummeted by another **62%**. Ex. 148 ¶¶19-20; 140; 142; 114, App. C.

27 **I. FDA’s Post-Class Period “Approval” of Avacopan**

28 Following the AdCom Meeting, the FDA sent a letter to ChemoCentryx stressing that “the

Agency does **not** consider that the use of avacopan to reduce or eliminate glucocorticoids has been established based on the data submitted to support your NDA.” Ex. 135.³ Schall recognized that the FDA “has us one step away from ‘checkmate’ at this point” and, with no other choice, he submitted a “major amendment” that made drastic concessions and admissions. Exs. 136, 137.

The FDA’s post-Class Period “approval” of avacopan required ChemoCentryx to admit, and state publicly, that avacopan “does **not** eliminate glucocorticoid use” and only can be used as an “adjunctive treatment...**in combination with** standard therapy including glucocorticoids.” Ex. 71. The FDA also forced ChemoCentryx to admit, and state publicly, that “serious cases of hepatic injury have been observed in patients taking [avacopan].” *Id.* Additionally, the FDA reiterated that none of ADVOCATE’s secondary endpoints were “validated,” barring Defendants from promoting avacopan based on them. Exs. 72; 137. Finally, the FDA required, as a condition to any approval, that ChemoCentryx conduct a five-year, post-marketing hepatotoxicity safety study (which is ongoing today) to determine whether the drug should be approved at all. Ex. 71.

III. LEGAL STANDARDS

As this Court has stated, summary judgment is only appropriate “when no genuine and disputed issues of material fact remain, and when, viewing the evidence most favorably to the non-moving party, the movant is clearly entitled to prevail as a matter of law.” *In re Twitter, Inc. Sec. Litig.*, 2020 WL 4187915, at *5 (N.D. Cal. Apr. 17, 2020). Where, as here, the evidence does not “unequivocally support” Defendants’ position, there is “conflict[ing]...evidence in the record” and “question[s] of fact” exist, the matter should be “left to the jury.” *In re Charles Schwab Corp. Sec. Litig.*, 2010 WL 1445445, at *5-7 (N.D. Cal. Apr. 8, 2010).

IV. TRIABLE ISSUES OF FACT ON FALSE OR MISLEADING STATEMENTS

A statement is misleading “if it would give a reasonable investor the ‘impression of a state of affairs that differs in a material way from the one that actually exists.’” MTD Order at 12

³ Defendants’ motion improperly relies on post-Class Period events, notwithstanding the Court’s order that they are not “relevant to whether Defendants made misrepresentations based on the ADVOCATE trial results.” *Daubert* Order at 8. Defendants additionally rely heavily on the FDA’s “approval” of avacopan, but the Court deferred ruling on its admissibility, explaining that it threatens “confusing the issues, misleading the jury, or wasting time.” *Id.* For the reasons discussed in its *Daubert* motions, Plaintiff will not introduce evidence of post-Class Period events at trial if Defendants are prohibited from doing the same. *See, e.g.*, ECF No. 237-3 at 12.

(quoting *Berson v. Applied Signal Tech., Inc.*, 527 F.3d 982, 985 (9th Cir. 2008)). “Even if a statement is not false, it may be misleading if it omits material information.” *Khoja v. Orexigen Therapeutics, Inc.*, 899 F.3d 988, 1008-09 (9th Cir. 2018). Once defendants “‘tout’ positive information to the market, ‘they [are] bound to do so in a manner that wouldn’t mislead investors,’ including disclosing adverse information that cuts against the positive information.” MTD Order at 20 (quoting *Arena*, 840 F.3d at 705-06). Generally, the question of “‘whether a public statement is misleading, or whether adverse facts were adequately disclosed is a mixed question to be decided by the trier of fact.’” *SEC v. Todd*, 642 F.3d 1207, 1220 (9th Cir. 2011). Assertions that statements were not misleading are therefore “rarely successful on a motion for summary judgment.” *SEC v. Mozilo*, 2009 WL 3807124, at *9 (C.D. Cal. Nov. 3, 2009).

A. Defendants’ False and Misleading Statements Are Actionable

The Court previously found that Defendants’ false and misleading statements about ADVOCATE and its results are actionable. *See* MTD Order at 12-29. Rehashing arguments already rejected, Defendants again contend that Plaintiff’s entire case can be summarily dismissed because the FDA ultimately “approved” avacopan well after the Class Period. They are wrong.

Besides overlooking the Court’s prior orders, Defendants ignore Supreme Court and Ninth Circuit law holding that statements touting positive drug-trial results are misleading where, like here, they omit adverse information, such as negative FDA feedback and negative trial data materially undercutting their statements. *See Arena*, 840 F.3d at 705, 708-09 (finding actionable statements touting clinical study results that failed to disclose the “FDA’s concerns,” as they “present[ed] a danger of misleading” investors); *Orexigen*, 899 F.3d at 1010 (finding actionable statements touting positive trial results that did not disclose that the FDA had indicated that the results were uncertain and unreliable); *Matrixx Initiatives, Inc. v. Siracusano*, 563 U.S. 27, 45 (2011) (finding actionable statements touting the safety of a drug that failed to disclose concerns raised by experts and negative safety data); *Zak v. Chelsea Therapeutics Int’l, Ltd.*, 780 F.3d 597, 609-10 (4th Cir. 2015) (finding actionable statements touting the “strength of [clinical trial] data” that “fail[ed] to disclose critical information received from the FDA”).

Drug approval does not alter this well-established rule. *See, e.g., Arena*, 840 F.3d at 709

(failure to disclose FDA concerns about FDA approval study actionable, even where FDA ultimately approved the drug); *Orexigen*, 899 F.3d at 1007, 1010 (failure to disclose FDA’s warning about unreliable data actionable, even where European regulator approved the drug); *In re Amylin Pharms., Inc., Sec. Litig.*, 2002 WL 31520051, at *5 (S.D. Cal. Oct. 10, 2002) (failure to disclose FDA warnings actionable, even where it approved the drug). FDA approval “after the end of the class period does **not** indicate that the statements were not false or misleading at the time they were made.” *Alberici v. Recro Pharma, Inc.*, 2021 WL 798299, at *7 (E.D. Pa. Mar. 1, 2021). Indeed, FDA approval after the class period “has **no bearing** on [p]laintiffs’ allegation that during the class period Defendants deceived investors.” *Tomaszewski v. Trevena, Inc.*, 482 F. Supp. 3d 317, 335 n.100 (E.D. Pa. 2020); *see also Hsu v. Puma Biotech., Inc.*, 2018 WL 11669124, at *2 (C.D. Cal. Oct. 24, 2018) (excluding evidence of FDA approval at trial). Consistent with these authorities, the Court stated during the *Daubert* hearing that it was “unlikely to allow post-class period evidence of FDA approval,” (Ex. 159 at 4:11-12), and noted in its *Daubert* Order that evidence of “approval” in this case threatens “confusing the issues, misleading the jury, or wasting time,” and, if admitted **at all**, would likely be subject to a jury instruction. *Daubert* Order at 8.

The facts of the Ninth Circuit’s decision in *Arena* closely match those at issue here. There, the defendant drug maker sought FDA approval to market a drug based on clinical studies. *Arena*, 840 F.3d at 701. In a private meeting with Arena, the FDA expressed concerns about the results of one of its studies. *Id.* at 702-03. Despite its concerns, the FDA permitted the trials to continue. *Id.* at 703. The fraud began to be revealed when, as here, the FDA published a briefing document ahead of an AdCom meeting disclosing its concerns. *Id.* The Ninth Circuit held that, while the drug was ultimately approved, Arena was obligated—but failed—to disclose the FDA’s concerns when it touted the drug’s “‘long-term safety and efficacy,’” which “were ‘demonstrated’ through ‘long-term preclinical toxicity and carcinogenicity studies.’” *Id.* at 707-08.

The Ninth Circuit rejected defendants’ argument that FDA “approval” means that defendants’ positive statements about their clinical studies were true, reasonable, and could not be fraudulent. *Id.* at 709. As the Ninth Circuit explained, “[i]t is the failure to disclose ‘issues’ and ‘concerns’ with the [] Study and the FDA’s interest in the outcome of those studies—**not** who was

ultimately right about the underlying science—that matters.” *Id.* “Defendants intentionally withheld information material to the market’s assessment of whether and when the FDA would likely approve [defendants’ drug]” and, thus, whether the FDA allowed trials to continue and ultimately approved the drug did **not** alter their disclosure duties. *Id.*

The Court has already applied this controlling law to this case and found that Defendants’ misstatements and omissions concerning ADVOCATE and Defendants’ interactions with the FDA were actionable. MTD Order at 13-19. In so doing, the Court rejected Defendants’ identical argument that avacopan’s ultimate FDA approval “believes any such assertion” that their statements were misleading. ECF No. 50 at 12, 24, 30. The Court held, as in *Arena*, that “regardless of whether the agency’s concerns would preclude the drug’s approval, they at least increased the risks that the drug would not be approved, would only be approved for a narrow label, or would not be as widely used by ANCA-associated vasculitis patients.” MTD Order at 16; *see also id.* at 15, 17.

B. Post-Class Period “Approval” Does Not Immunize Defendants From Liability

Defendants, nevertheless, again argue that because the FDA ultimately “approved” avacopan, their statements cannot be false or misleading. Mot. at 11-17. In addition to ignoring Ninth Circuit law and this Court’s prior orders, this argument fails for several additional reasons.

First, the FDA **never** approved ChemoCentryx’s Class Period NDA. Rather, it approved—after the Class Period and following a “major amendment”—a severely restricted **indication** for avacopan, replete with limitations, warnings, and conditions. Ex. 71. The FDA found and required ChemoCentryx to state publicly that avacopan “does **not** eliminate glucocorticoid use,” with its use restricted to “adjunctive treatment” and **not** for maintenance therapy. *Id.* The FDA further rejected ChemoCentryx’s secondary endpoints altogether and required it to admit that “**serious cases of hepatic injury**” were observed on avacopan during ADVOCATE. *Id.* Additionally, the FDA mandated—as a condition to any “approval”—that Defendants conduct an extensive, five-year safety study that is still ongoing. *Id.* Defendants’ claims of “approval” are grossly overstated.

Second, the FDA never “agreed” to ADVOCATE’s design. As Dr. Kanagala admitted, the FDA “**disagree[d]** with the study design and the endpoints,” but yet Defendants “went ahead with the same study design.” Ex. 66. Dr. Walton, an expert of FDA affairs, concurs: the regulatory

record reflects that the FDA disagreed with ADVOCATE's design, disagreed with its SAP, and never approved the Study Protocol. Ex. 150 ¶¶32-44. Defendants' self-serving claims of an "agreement" on the overall study and a "regulatory presumption" are factually wrong.⁴

Third, Defendants' data manipulation and concealment of adverse reports from the FDA precludes them from pointing to any "approval" as evidence of their "reasonableness" or "good faith." *See Provenz v. Miller*, 102 F.3d 1478, 1491 (9th Cir. 1996) ("If it is true that defendants withheld material information from their accountants, defendants will not be able to rely on their accountant's advice as proof of good faith."). The FDA would not have approved avacopan at all had ChemoCentryx not manipulated the trial data to manufacture "superiority" at week-52. Ex. 66 at 846. And the FDA would have halted ADVOCATE had it received Dr. Maddrey's hepatotoxicity report, which Defendants also hid from the FDA. Ex. 164 at 92:21-93:2; 172.

Fourth, the challenged statements are not mere "opinions." Mot. at 12 (citing *Omnicare, Inc. v. Laborers Dist. Council Const. Indus. Pension Fund*, 575 U.S. 175, 185 (2015)). As the Court has held, "[a]ll of the statements Defendants identify contain **both** facts and opinions" and, for the vast bulk of them, "Plaintiff challenges as misleading only the facts included in the statement, not the opinions." MTD Order at 21-22. The Court's prior order is consistent with Ninth Circuit law, which has repeatedly held that statements, such as those at issue here, are not "opinions." *See ThermoLife Int'l, LLC v. Gaspari Nutrition Inc.*, 648 Fed. App'x 609, 615 (9th Cir. 2016) (statements about whether "products were 'safe'" are "statements of fact, not opinion"); *In re QuantumScape Sec. Class Action Litig.*, 580 F. Supp. 3d 714, 739 (N.D. Cal. 2022) (statements about what "data demonstrat[es]" and "testing showed" are "not opinions").

Here, too, Defendants' statements concerned "facts"—including, among others, that (i) avacopan "had fewer adverse events and fewer serious adverse events" (Ex. 26 at 409); (ii) ADVOCATE's secondary endpoints were "validated," (Ex. 10 at 823); (iii) ADVOCATE achieved its primary endpoints (Ex. 7 at 1); (iv) avacopan was a "monotherapy" and "eliminated

⁴ Defendants mischaracterize a snippet from the November 2016 minutes, which is limited to **one** aspect of **one** of the endpoints—**not** the entire ADVOCATE study—as Dr. Walton explained and Kanagala recognized. Exs. 66; 150 ¶33. ChemoCentryx **never** obtained a "Special Protocol Assessment," which "is the controlling mechanism under which companies and the FDA reach full agreement on study design." Ex. 170 at 263:9-264:7.

prednisone” (Exs. 23 at 379; 12 at 851)⁵; and (v) the FDA had “not highlighted any particular issues.” Ex. 31 at 559. These statements were patently false or, at minimum, highly misleading.

In any event, *even if* Defendants’ statements could be recast as opinions, they are still actionable. *Omnicare* did not create a loophole for “opinion” statements. Rather, “a reasonable investor expects that the issuer’s opinion ‘fairly aligns with the information in the issuer’s possession at the time.’” *In re SVB Fin. Grp. Sec. Litig.*, 2025 WL 1676800, at *10 (N.D. Cal. June 13, 2025). Under *Omnicare*, there are three ways to establish liability for opinion statements: “(1) a theory of material misrepresentation (*i.e.*, the speaker did not hold the belief professed and the belief was objectively untrue), (2) a theory that a statement of fact contained within an opinion statement is materially misleading (*i.e.*, the opinion contained ‘embedded statements of fact’ that are false); and (3) a theory of omission (*i.e.*,...facts showing that the company knew undisclosed information that seriously undermined the basis for its opinion).” *Id.* at *16. Each applies here.

All of the challenged statements (even if recast as “opinions”) contain “embedded facts” that render the statements false or misleading. *See Omnicare*, 575 U.S. at 185 (“[E]mbedded statements of fact...may be read to affirm not only the speaker’s state of mind...but also an underlying fact.”). Additionally, Defendants omitted material facts that “undermined” their “factual basis for their belief”—including, among others, “the FDA’s concerns about the trial’s safety and efficacy metrics” and “the FDA’s concerns that the trial could not support a comparative analysis of the safety of avacopan and standard-of-care steroid treatment.” MTD Order at 22-24. And there is ample evidence in the record showing that Defendants did not actually believe their statements, which were objectively false. *See supra* at 3-8.

As the Court explained, “an investor would expect that the speaker’s proposed interpretation of trial results had not already been undermined by the agency tasked with evaluating the NDA.” MTD Order at 24; *see also Omnicare*, 575 U.S. at 188-89 (an opinion is actionable if known “that the Federal Government was taking the opposite view”); *In re Atossa Genetics Inc Sec. Litig.*, 868 F.3d 784, 801-802 (9th Cir. 2017) (actionable omission where undisclosed “FDA

⁵ Defendants’ expert *admitted* that avacopan was *not* used as a “monotherapy” in ADVOCATE, but rather “steroids” were used with avacopan to treat AAV. Ex. 180 at 452:18-453:4.

concerns” did not “fairly align” with defendants’ opinion); *In re BioMarin Pharm. Inc. Sec. Litig.*, 2022 WL 164299, at *2 (N.D. Cal. Jan. 6, 2022) (statements that “we’ve had fairly clear dialogue with [FDA]” actionable, even if opinions); *Gerneth v. Chiasma, Inc.*, 2018 WL 935418, at *5 n.2 (D. Mass. Feb. 15, 2018) (opinions actionable where defendants omitted FDA concerns “tending to undermine the accuracy of the statement”).

Finally, instead of addressing controlling Ninth Circuit law and the Court’s prior holdings, Defendants point to *In re Philip Morris Int’l Inc. Sec. Litig.*, 89 F.4th 408 (2d Cir. 2023)—an out-of-circuit case that is readily distinguishable from the factual record here.⁶ In *Philip Morris*, the defendants sought FDA approval to market a smokeless cigarette product as “safer, healthier, and less risky” and cited studies that they described as showing “potential” and “likely” health benefits as compared to traditional cigarettes. *Id.* at 414-15, 421-22. The Court dismissed defendants’ statements about their study results because the FDA “endorsed [their] view of the data,” with the FDA’s findings “mirror[ing] [d]efendants’ carefully measured statements.” *Id.* at 421-22.

Unlike in *Philip Morris*, the FDA **never** “endorsed” Defendants’ view of the data. Rather, the FDA concluded—contrary to Defendants’ view of the data—that avacopan “does **not** eliminate glucocorticoid use,” should only be used “in combination with” standard therapy, and causes “serious cases of hepatic injury.” Ex. 71. Also unlike in *Philip Morris*, the FDA’s findings did **not** “effectively mirror” Defendants’ statements to investors during the Class Period; rather, the FDA’s findings were diametrically opposed to what Defendants told investors. *Compare* Ex. 66 (GTI not validated), *with* Ex.10 at 823 (GTI is “validated”). Plus, Defendants’ statements to investors in this case were **not** “carefully measured”; rather, they asserted, for example, that there was “irrefutable” and “definitive evidence statistically that [avacopan] was superior in reducing glucocorticoid-related toxicities,” which the FDA strongly disagreed with. Exs. 8 at 775; 10 at 823; 126 at 280. None of these contradictions were present in *Philip Morris*, which is inapplicable here.⁷

⁶ Defendants also rely upon the same cases they previously cited in their prior failed motions. *See* ECF Nos. 50, 57 (citing same cases). *In re Rigel Pharms., Inc. Sec. Litig.*, 697 F.3d 869 (9th Cir. 2012) remains inapposite, as it consisted of bare allegations that defendants should have used “[p]laintiff’s chosen statistical methodology.” *Id.* at 877. In *Tongue v. Sanofi*, 816 F.3d 199 (2d Cir. 2016) there was **no** “conflict” between the FDA’s and the issuer’s statements. *Id.* at 211-14.

⁷ Defendants’ other cases are also readily distinguishable. In *Pardi v. Tricida, Inc.*, 2024 WL

C. Triable Issues Of Fact Demonstrate Scienter

“Generally, scienter should not be resolved by summary judgment.” *Provenz*, 102 F.3d at 1489. This is particularly true in a case, such as this one, that involves the PSLRA, in which “it is generally more difficult to overcome a motion to dismiss than a motion for summary judgment.” *In re Homestore.com, Inc. Sec. Litig.*, 347 F. Supp. 2d 769, 784 (C.D. Cal. 2004).

“Plaintiffs can ‘establish scienter by proving either actual knowledge *or* recklessness.’” *Provenz*, 102 F.3d at 1490. As the Ninth Circuit has explained, “[w]hen the defendant is aware of the facts that made the statement misleading, he cannot ignore the facts and plead ignorance of the risk.” *S.E.C. v. Platforms Wireless Int’l Corp.*, 617 F.3d 1072, 1094 (9th Cir. 2010). “Importantly, ‘[s]cienter can be established by direct *or* circumstantial evidence.’” *Davis v. Yelp, Inc.*, 2021 WL 4923359, at *12 (N.D. Cal. Sept. 17, 2021). Here, there is ample scienter evidence.

First, Defendants received “contemporaneous reports” and had access to “data” that “contradict[ed] the[ir] statement[s]” to investors—which is “the most direct way” to prove scienter. *Nursing Home Pension Fund, Loc. 144 v. Oracle Corp.*, 380 F.3d 1226, 1230 (9th Cir. 2004). Before and during the Class Period, Defendants received, among other things:

- FDA correspondence identifying significant deficiencies in the ADVOCATE, making clear that the agency “disagree[d] with the study design and the endpoints” and had grave concerns that the study’s results were “confound[ed]” and “bias[ed]” (Exs. 66; 70; 68-69);
- DMC unanimous letters warning of avacopan’s hepatotoxicity, including “gold standard” evidence of “potentially fatal risks of...hepatotoxicity associated with [avacopan],” and how it was “remarkable to observe cases of marked drug-induced liver injury this early in a new drug’s development” (Exs. 48; 51-52; 38-47; 49-50); and
- Dr. Maddrey’s reports raising “ongoing concerns [about avacopan’s] liver toxicity,” including that several “cases from the study represent clear instances of serious drug induced liver injury and will be FDA concerns.” Exs. 57; 169 at 167:12-19; 58-60.

1056013, *8-9 (N.D. Cal. Mar. 11, 2024), unlike here, defendants **had** adequately disclosed to investors the FDA’s concerns, including that their NDA “relied on ‘an unvalidated surrogate endpoint,’” and defendants “did not represent that there was no controversy with the FDA.” In *Thant v. Rain Oncology Inc.*, 2025 WL 588994, at *2 (N.D. Cal. Feb. 24, 2025), also unlike here, defendants did **not** omit any conflicting data, findings, or warnings from the FDA. *Bazzelle v. Novocure Ltd.*, 2025 WL 843668 at *10-11 (S.D.N.Y. Mar. 18, 2025) (same). In *Strezsak v. Ardelyx Inc.*, 2024 WL 1160900, at *5 (N.D. Cal. Mar. 18, 2024) the court specifically found that “the FDA expressed **no** explicit concerns about the trial.” Finally, in *Pitman v. Immunovant, Inc.*, 2024 WL 1342737, at *9 (E.D.N.Y. Mar. 29, 2024), the court did “**not** rely on the FDA approval...to make any findings or conclusions about the veracity of [d]efendants’ statements.”

1 Additionally, Defendants were told that their public statements were false and misleading.
 2 Among others, the DMC warned Defendants that: (i) the ADVOCATE Press Release said “very
 3 [l]ittle about hepato-toxicity and other -related side effects which bothered us a great deal” (Ex.
 4 43); (ii) “[t]he DMC has long been concerned that [ChemoCentryx’s] safety reporting downplays
 5 potential drug toxicities” (Ex. 40); and (iii) ChemoCentryx faced the “corporate risk of [a securities
 6 fraud lawsuit for] not revealing a hepatotoxicity concern which later is revealed by the FDA.” Exs
 7 42; 165 at 270:19-272:15. Dr. Kelleher also raised concerns about its disclosures, to which Schall
 8 told her she was “too vocal” and to “stop talking” about liver toxicity. Ex. 65 at 54:4-57:5.

9 Defendants’ receipt of reports documenting the FDA’s concerns is compelling scienter
 10 evidence. *See Arena*, 840 F.3d at 708 (scienter based on defendants’ “failure to inform the market
 11 about the risk of non-approval or delayed approval based on the FDA’s concerns”); *BioMarin*,
 12 2022 WL 164299, at *4, *13 (scienter given “concrete warning” from the FDA); *see also Zak*, 780
 13 F.3d at 609-10 (scienter based on adverse FDA communications about sufficiency of clinical
 14 trials).⁸ And contrary to what Defendants say in their motion (Mot. at 15), the FDA “disagree[d]
 15 with the study design and the endpoints” (Ex. 66), and there is no “regulatory presumption.”

16 **Second**, avacopan’s import to ChemoCentryx’s continued survival, including its ability to
 17 secure financing, is further evidence of scienter. MTD Order at 31-32 (Defendants were
 18 “financially motivated to mislead investors regarding the strength of the trial results due to
 19 ChemoCentryx’s financial circumstances”); *see also BioMarin*, 2022 WL 164299, at *14 (scienter
 20 where drug submitted for approval “was going to be a significant and lucrative product”);
 21 *Hatamian v. Adv. Micro Devices, Inc.*, 87 F. Supp. 3d 1149, 1163 (N.D. Cal. 2015) (scienter where
 22 product was “critical” to defendant’s “financial success”).

23 **Third**, Defendants’ manipulation of ADVOCATE’s data is also compelling scienter
 24 evidence. As this Court explained in the *Daubert* Order, Defendants’ data manipulation “supports
 25

26 ⁸ The case Defendants rely upon to argue otherwise is easily distinguishable. In *Kader v. Sarepta*
 27 *Therapeutics, Inc.*, 887 F.3d 48 (1st Cir. 2018) defendants **disclosed** to investors that the FDA
 28 expressed “uncertain[ty] whether the...biomarker data will be persuasive enough to serve as a
 surrogate endpoint that is reasonably likely to predict clinical benefit.” *Id.* at 53. Here, in contrast,
 Defendants **concealed** from investors the FDA’s findings that the validity of “several biomarkers”
 in ADVOCATE is “unclear,” and the “results from [the GTI] endpoint will **not** be utilized to
 support regulatory or labeling decisions.” Ex. 62 at 845.

1 the scienter element of Plaintiff’s claims” and is “generally relevant to Defendants’ knowledge
 2 that their alleged misrepresentations were false in this case—i.e., that avacopan in fact failed to
 3 achieve statistically significant superiority.” ECF No. 289 at 10; *see also In re Entropin, Inc. Sec.*
 4 *Litig.*, 487 F. Supp. 2d 1141, 1148-52 & n.10 (C.D. Cal. 2007) (“unblinding” and “manipulation”
 5 of clinical data created a “material issue of fact” on scienter).

6 Defendants’ contention that their data manipulation is untethered to their fraud is factually
 7 and legally wrong. Absent the manipulation, Defendants would not have been able to report the
 8 “superiority” outcome at the center of the case. Exs. 108-111. In addition, there is no requirement
 9 that the manipulation be disclosed to the public to count toward scienter. *See Amylin*, 2002 WL
 10 31520051, at *7-8 (defendants’ manipulation of safety database for clinical studies supported
 11 finding of scienter even where the manipulation was not the subject of an advisory committee
 12 meeting that disclosed the fraud). Defendants’ argument otherwise also ignores that courts must
 13 “consider the totality of circumstances” when evaluating scienter, including **both** direct and
 14 circumstantial evidence, and cannot “close their eyes to circumstances that are probative of
 15 scienter viewed with a practical and common-sense perspective.” *S. Ferry LP, No. 2 v. Killinger*,
 16 542 F.3d 776, 784 (9th Cir. 2008); *see also Nathanson v. Polycom, Inc.*, 87 F. Supp. 3d 966, 979-
 17 80 (N.D. Cal. 2015) (circumstantial scienter evidence includes cover-up evidence).⁹

18 Contrary to Defendants’ self-serving assertions, Schall **was** aware of ChemoCentryx’s data
 19 manipulation. On November 7, 2019, Schall sent Dr. Bekker a private text message that instructed
 20 him to immediately “call” Schall and consult with him after database-lock if the unblinded results
 21 of ADVOCATE showed that it failed to demonstrate “superiority” at week-52—all in violation of
 22 ADVOCATE’s Protocol. Exs. 107; 164 at 476:23-477:7. Schall’s testimony that Bekker did **not**
 23 follow his boss’s order is unbelievable and, at most, a credibility question for the jury. *Terra Ins.*
 24 *Co. v. New York Life Inv. Mgmt. LLC*, 717 F. Supp. 2d 883, 892 (N.D. Cal. 2010); *see also Bing*
 25 *Li v. Aeterna Zentaris, Inc.*, 2016 WL 827256, at *3 (D.N.J. 2016) (“It is highly improbable that
 26 Aeterna had not known that the data sample was modified in violation of the usual policy.”).

27
 28 ⁹ *Espy v. J2 Glob., Inc.*, 99 F.4th 527 (9th Cir. 2024) concerned allegations of an employee’s efforts to get his girlfriend a visa and other perks that were totally unrelated to misstatements about an acquisition. *Id.* at 536-38. Nothing like those facts is present here.

1 In any event, Drs. Bekker’s and Yue’s knowledge of the data manipulation is *also* imputed
 2 to ChemoCentryx. Courts hold that “the state of mind of any individual agent who authorized,
 3 requested, commanded, furnished information for, prepared ... reviewed, or approved [a] statement
 4 in which the misrepresentation was made before its utterance or issuance could be attributed to a
 5 corporation for determining whether it had sufficient scienter under Section 10(b).” *Sec. & Exch.*
 6 *Comm’n v. City of Victorville*, 2018 WL 3201676, at *3 (C.D. Cal. Jan. 24, 2018). Here, the
 7 evidence shows that Dr. Bekker, who was the “most senior medical officer at ChemoCentryx”
 8 during the Class Period, furnished information for, prepared, and reviewed ChemoCentryx’s
 9 disclosures to investors—including the ADVOCATE Press Release published just two weeks after
 10 the data manipulation. Exs. 139-141; 65 at 22:22-23:24. Likewise, Dr. Yue—the Company’s VP
 11 of Biometrics and a direct report to Defendant Schall—was heavily involved in all facets of the
 12 data manipulation and similarly furnished information for ChemoCentryx’s disclosures to
 13 investors, including the ADVOCATE Press Release. *See, e.g.*, Exs. 108-111.

14 **V. DEFENDANTS ARE NOT ENTITLED TO PARTIAL SUMMARY JUDGMENT**

15 **A. The Parties’ Loss Causation Dispute Presents Triable Issues of Fact**

16 “To survive summary judgement, ... Plaintiffs need only point to evidence supporting a
 17 reasonable finding that the challenged statements were *one* substantial cause for the stock-price
 18 declines.” *Twitter*, 2020 WL 4187915, at *16. “[L]oss causation is a ‘context-dependent’ inquiry,”
 19 and “there are an ‘infinite variety’ of ways” to establish loss causation, including corrective
 20 disclosures. *Mineworkers’ Pension Scheme v. First Solar Inc.*, 881 F.3d 750, 753 (9th Cir. 2018).
 21 Corrective disclosures can take the form of an analysis of “complex[]” data previously available
 22 to investors but requiring “great effort” to analyze. *In re BofI Holding, Inc. Sec. Litig.*, 977 F.3d
 23 781, 791, 795 (9th Cir. 2020). “[S]ummary judgment” on loss causation “is inappropriate where
 24 an expert’s testimony supports the non-moving party’s case.” *Sonner v. Schwabe N. Am., Inc.*, 911
 25 F.3d 989, 992 (9th Cir. 2018) (quoting *Provenz*, 102 F.3d at 1490).

26 Defendants’ challenge to loss causation fails. On May 6, 2021, the FDA, ChemoCentryx,
 27 and an AdCom of expert clinicians and scientists convened a meeting to discuss the avacopan
 28 NDA and ADVOCATE’s results. NASDAQ halted trading all day due to the import of the

1 meeting, which was livestreamed online. The meeting revealed previously concealed facts and
 2 caused an immediate stock price decline of **62%**, when trading resumed. Ex. 148 at Ex. 4.

3 There is ample expert and fact evidence from which a reasonable jury could “trace” the
 4 May 6 disclosures “back to the very facts about which the defendant lied” and thus find a “causal
 5 connection” to the stock price decline on May 7. *See id.* at 137-61; *see also First Solar*, 881 F.3d
 6 at 753. Defendants’ contrary argument (Mot. at 18-23) ignores the Court’s prior orders, misstates
 7 the legal standard and their burden, and raises disputed factual issues that only a jury can resolve.

8 **First**, the Court has twice rejected the substance of Defendants’ argument in procedural
 9 postures more favorable to Defendants—in which, unlike here, the evidence is weighed. At class
 10 certification, Defendants attempted to rebut price impact on May 6-7 by claiming that “the
 11 allegedly concealed information had already been disclosed.” *See* ECF No. 87 at 4. The Court
 12 weighed the evidence and concluded that “Defendants failed to sever the link.” CC Order at 5-6,
 13 9. The Court has also held that all of Dr. Cain’s opinions are admissible, including his opinions
 14 that the May 6 disclosure “revealed additional corrective information” and caused the abnormal
 15 stock price decline on May 7. *Daubert* Order at 30-36; Ex. 148 at ¶¶137-58. Dr. Cain has explained
 16 the facts that were revealed at the AdCom Meeting on May 6, how they relate to Defendants’
 17 misstatements, and how they caused the abnormal stock drop decline on May 7. *Id.* Such expert
 18 testimony that a “company-specific decline” occurred and that “a causal connection exists”
 19 suffices to create a “genuine dispute.” *Twitter*, 2020 WL 4187915, at *17.¹⁰

20 **Second**, a reasonable jury could find that the 300+ transcript pages of analysis at the May 6
 21 AdCom Meeting revealed information that was not known or fully understood previously and not
 22 fully reflected in ChemoCentryx’s stock price. While Defendants cite *BofI*, for the requirement
 23 that a corrective disclosure must be “new” (Mot. at 19-20), they omit *BofI*’s important clarification
 24 that an analysis of previously available information “can *still* be ‘new’ if the market has not
 25 previously understood its significance” or if it is “not yet reflected in the company’s stock price.”
 26 *BofI*, 977 F.3d at 791, 795. *BofI* adopted a “case-by-case” “flexible approach,” not a “bright-line

27
 28

 10 Unlike here, *In re REMEC Inc. Sec. Litig.*, 702 F. Supp. 2d 1202 (S.D. Cal. 2010) (Mot. at 19),
 granted summary judgment because plaintiff’s expert was excluded. *Id.* at 1273-75.

rule.” *Id.* at 795.¹¹ The relevant circumstances include “the complexity of the data and its relationship to the alleged misstatements” and the “great effort needed to locate and analyze it,” (*id.*), and whether it is “easily digestible in its native format” and “understandable to a lay person,” *In re Genius Brands Int’l, Inc. Sec. Litig.*, 97 F.4th 1171, 1186-87 (9th Cir. 2024).

A reasonable jury could find that the disclosures in the Briefing Book were complex, not easily digestible to lay persons, and required great effort to analyze. They pertained to scientific and technical subject-matters, and their complexity is precisely why an AdCom was convened. The FDA provided those experts 22 days to digest the FDA Briefing Book—far more than the one day given to investors between its release on May 4 and market close on May 5.

The AdCom experts’ views and votes were also “new information.” *See In re AVEO Pharms., Inc. Sec. Litig.*, 2017 WL 5484672, at *2, *5-7 (D. Mass. Nov. 14, 2017).¹² A reasonable jury could find, among other things, that the FDA and the AdCom’s discussion to be “more authoritative” than FDA staff, and thus find loss causation. *See In re Apollo Grp., Inc. Sec. Litig.*, 2010 WL 5927988, *1 (9th Cir. June 23, 2010) (reversing judgment as a matter of law on loss causation because analyst report was “more authoritative” than prior news articles). As in *AVEO*, ChemoCentryx’s stock price dropped both after the briefing book and then again after the AdCom Meeting, consistent with a “series of partial disclosures.” *BofI*, 977 F.3d at 790.¹³

Defendants *admit* that the AdCom “discussion and vote” were “new,” but then add that they are “thus non-corrective.” Mot. at 19. The Court has already rejected this argument, holding Dr. Cain may testify that “the result of the AdCom vote is not a nonfraudulent cause of the stock

¹¹ *BofI* found that the disclosures were “new,” but were not plausibly corrective because they were authored by “anonymous short-sellers who had a financial incentive to convince others to sell.” 977 F.3d at 797. There is no conflict-of-interest issue here. Further, *In re Mylan N.V. Sec. Litig.*, 666 F. Supp. 3d 266 (S.D.N.Y. 2023) (Mot. at 19, 23), involved a “failure to ‘disaggregate,’” (*id.* at 325)—an objection the Court already rejected here. ECF No. 289 at 33-36.

¹² Defendants say “in *AVEO* (unlike here), the FDA’s presentation to the AdCom was not published before the meeting.” Mot. at 22 n.11. However, in *AVEO* as here, the FDA’s briefing book was published two days before the AdCom Meeting. 2017 WL 5484672, at *2.

¹³ In contrast to this case and *AVEO*, in the cases cited by Defendants (Mot. at 21), there was *no* stock drop after the publication of the briefing book—only after the AdCom Meeting. *In re FibroGen Sec. Litig.*, 2024 WL 1064665 (N.D. Cal. Mar. 11, 2024) (applying different standard at class certification); *Shash v. Biogen Inc.*, 2025 WL 928779, at *2 (D. Mass. Mar. 27, 2025) (briefing book “provided an ‘effusive’ endorsement”). Finally, *In re Sanofi Sec. Litig.*, 87 F. Supp. 3d 510, 543 (S.D.N.Y. 2015) (Mot. at 21), addresses falsity, not loss causation, and is inapposite.

price drop that needs to be disaggregated,” but rather a “foreseeable” result of facts Defendants concealed. *Daubert* Order at 35-35; *see First Solar*, 881 F.3d at 754 (loss causation exists when “underlying facts concealed by fraud ... foreseeably caused the plaintiff’s loss”); *In re Gilead Scis. Sec. Litig.*, 536 F.3d 1049, 1058 (9th Cir. 2008) (loss causation exists when FDA warning letter caused an earnings miss, even though market “failed to appreciate” warning letter when first disclosed). Because the fraud foreseeably caused the AdCom’s reaction, Defendants’ argument—also raised (and rejected) in their *Daubert* motion—that its reaction “reflected the materialization of a known risk” (Mot. at 23) fails. *See Twitter*, 2020 WL 4187915, at *17 & n.19.

Third, a reasonable jury could find that the FDA Briefing Book did not “fully” correct the fraud. Defendants’ contentions otherwise amount to a truth-on-the-market argument, which is an affirmative defense. “Plaintiffs’ burden is to describe how the falsity of the defendant’s misstatement was revealed to the market, **not** to describe all the ways in which it was **not** revealed.” *Grigsby v. BofI Holding, Inc.*, 979 F.3d 1198, 1206 (9th Cir. 2020). To sustain a “truth-on-the-market” defense, Defendants bear a “heavy burden of proof,” *Provenz*, 102 F.3d at 1492-93, to show a prior correction was “transmitted to the public with a degree of intensity and credibility sufficient to effectively counterbalance any misleading impression.” *In re Facebook, Inc. Sec. Litig.*, 87 F.4th 934, 951 (9th Cir. 2023). Defendants cannot carry that burden, as, at minimum, there are disputed facts.¹⁴

Contrary to Defendants’ assertions, the May 4 and May 6 disclosures were not informationally identical.¹⁵ Defendants’ claim that Table 2 of the Briefing Book was redacted

¹⁴ *In re Nektar Therapeutics Sec. Litig.*, 34 F.4th 828 (9th Cir. 2022) (Mot. at 19), held that a second clinical trial with different results was not corrective of the results of a prior trial. *In re Oracle Corp. Sec. Litig.*, 627 F.3d 376 (9th Cir. 2010) (Mot. at 19), held that an earnings miss was not corrective because undisputed evidence showed it was caused by macroeconomic conditions entirely unrelated to the fraud. *Id.* at 392-93. *Evanston Police Pension Fund v. McKesson Corp.*, 2021 WL 4902420 (N.D. Cal. Oct. 21, 2021) (Mot. at 20), involved disclosures about third parties, not the defendant. *Id.* at *5. Here, all the corrective disclosures are about Defendants.

¹⁵ Among other things, new information was revealed on May 6 about: (i) liver injury, with the FDA’s DILI lead stating one case “does meet Hy’s law” and was “inconsistent” with another drug. (Exs. 133 at 071-72; 148 ¶140), which was additive to Briefing Book’s stating the case met the “laboratory criteria,” (Ex. 126 at 283), and Schall’s May 4 denial of any Hy’s Law case, (Ex. 182 at 25); (ii) confounding effects of steroids in the avacopan arm, including that the “mean prednisone dose” (previously reported) was “an underestimation,” (Exs. 133 at 158; 148 ¶138); and (iii) confounding effects of the lack of rituximab maintenance, including that off-label maintenance had been “standard of care.” Exs. 133 at 176-77, 185-86; 148 ¶139.

1 because of “errors” is false and, at best, a factual dispute. Mot. at 8. Defendants made the same
 2 argument to the FDA—unsuccessfully—with the FDA explaining that: ChemoCentryx’s proposed
 3 errata “*does not correct an error*” and FDA does “*not agree that key facts are missing.*” Ex. 127.
 4 ChemoCentryx then shifted gears, insisting that it contains trade secrets, which was the eventual
 5 basis for the redaction. Exs. 128; 126 at 292-96 (redacting based on 5 U.S.C. § 552(b)(4)).

6 Defendants’ truth-on-the-market defense also fails because, as the Court has recognized,
 7 Defendants “continued to reassure analysts” and investors between May 4 and 6. *See Daubert*
 8 *Order* at 34; *No. 84 Emp.-Teamster Joint Council Pension Tr. Fund v. Am. W. Holding Corp.*, 320
 9 F.3d 920, 935 (9th Cir. 2003). Armed with advanced knowledge of the FDA’s Briefing Book,
 10 Defendants planned an “outreach” to analysts and investors aimed at “*leveling the playing field*
 11 *between CCXI and FDA perspectives*” and thus dampening the “market reaction to the AdCom
 12 briefing documents.” Ex. 130. Schall and ChemoCentryx’s CFO scheduled a “*grueling day*” of
 13 seven analyst calls on May 4 alone. Exs. 132; 131. Plus, when asked whether Defendants’ May 4
 14 response to the FDA’s briefing book would contain the company’s “answers to FDA’s questions,”
 15 Schall advised investors to “*wait for May 6.*” Ex. 37 at 867. By telling investors to wait until
 16 May 6, Defendants created a further causal “link.” *AVEO*, 2017 WL 5484672, at *2, *7.¹⁶

17 **B. There Is A Disputed Issue of Material Fact Whether ChemoCentryx Violated**
 18 **the ADVOCATE Protocol By Not Using BVAS 3**

19 Defendants next assert that it is “undisputed” that “there was no BVAS-related protocol
 20 violation.” Mot. at 24. Not so. The Protocol for the ADVOCATE specifically stated that “BVAS
 21 version 3 *will* be used in this study.” Ex. 112 at 429. But BVAS 3 was *not* used, as detailed in the
 22 expert report of Dr. Helfgott. Ex. 155 ¶¶99-103. Defendants were well aware of this fact, which
 23 they intentionally hid. Dr. Merkel admitted we “*can’t really call this BVAS 3,*” to which Bekker
 24 agreed, but urged his colleagues *not to “publicize widely”* this fact. Ex. 98. Defendants further
 25 knew—and also hid from investors—that, when the *actual* BVAS 3 was used, ADVOCATE *failed*
 26 to meet its primary endpoints. Exs. 98; 174 at 102:15-103:5, 104:14-105:1. As the FDA explained
 27
 28

¹⁶ Defendants cite no support for their assertion that Plaintiff is required to plead Defendants’ statements to analysts between May 4 and 6 are actionable misstatements. Mot. at 22 & n.11.

1 during the AdCom Meeting, by failing to abide by the Protocol—not using BVAS 3 and ignoring
 2 “persistent disease”—ChemoCentryx “underestimate[d] true disease activity.” Ex. 134 at 467.

3 Equally baseless is Defendants’ attempt to show that ChemoCentryx’s protocol violation
 4 was disclosed to investors. Defendants have previously raised this *same* argument, which the Court
 5 has rejected. *See* ECF No. 56. The Protocol and the *NEJM* did not reveal the truth: both stated that
 6 “BVAS version 3 *will be used in this study*.” Ex. 163 at 429; DX17. The *JMIR* article—which
 7 was not authored by ChemoCentryx and a mere “pre-print” (i.e., not peer-reviewed)—again stated
 8 that ChemoCentryx used “BVAS version 3.” DX4 at 563 The pre-print’s reference to a “slight
 9 modification” did not remotely reveal the truth, including: that (i) “ChemoCentryx’s reported
 10 BVAS remission results were *not* measured in conformance with ADVOCATE’s protocol”; and
 11 (ii) “when BVAS 3 is used as specified by the protocol, avacopan did *not* demonstrate statistical
 12 superiority to the standard of care at either week 26 or week 52.” Exs. 148 ¶¶49-55; 100. On these
 13 facts, it cannot be said that Defendants have borne their “heavy burden” of proving that the omitted
 14 truth was transmitted with an “intensity and credibility sufficient to effectively counterbalance any
 15 misleading impression.” *See Provenz*, 102 F.3d at 1493; *see also Miller v. Thane Int’l, Inc.*, 519
 16 F.3d 879, 887 (9th Cir. 2008) (“Ordinarily, omissions by corporate insiders are not rendered
 17 immaterial by the fact that the omitted facts are otherwise available to the public.”).

18 **C. Defendants Are Not Entitled To Summary Judgment On Their “Truth-on-the-**
 19 **Market Defense” About Steroid Use And Efficacy In The ADVOCATE Trial**

20 In their motion, Defendants also try (Mot. at 18) a “truth-on-the-market” defense based on
 21 their claim that investors knew of the rampant non-study-supplied steroid used *to treat AAV* in the
 22 ADVOCATE and that avacopan was *not* superior to standard of care. Their attempt fails.

23 *First*, Defendants ignore the Court’s prior rulings. Defendants previously made these *same*
 24 truth-on-the-market arguments based on the *same* evidence. The Court weighed the evidence and
 25 rejected them, explaining that the disclosures Defendants point to as supposedly revealing the
 26 truth, in fact, “omit[ted] key details,” including that “64% of avacopan patients were prescribed
 27 prednisone specifically because steroids were needed to treat and control their vasculitis” and
 28 “Defendants counted remitted avacopan patients as ‘responders’ to avacopan ... even if they

1 required significant treatment with out-of-study steroids in order to manage their disease.” CC
 2 Order at 10. The Court further found that the disclosures that Defendants point to as supposedly
 3 revealing the truth about the “subgroup data,” in reality, “did *not* disclose facts relevant to the
 4 alleged misrepresentations” and “omit[ted] the relevant implications of these results”—including,
 5 that avacopan failed to achieve statistically significant superiority against “the only subgroup of
 6 steroid patients actually receiving ‘standard of care’ maintenance therapy.” *Id.* at 11.

7 **Second**, Defendants’ recycled truth-on-the-market arguments, even if considered anew,
 8 fare no better. Defendants’ exhibits show only that patients in the “avacopan” arm of ADVOCATE
 9 could or did receive some steroids for a variety of reasons—including the four-week taper at the
 10 start of the study, steroids co-administered with rituximab, and treatment of other conditions. *E.g.*,
 11 DX 4 at 13-14. Defendants further ignore that their public Protocol said non-study steroids to treat
 12 AAV “*must be avoided as much as possible*,” and the *NEJM* article said steroid use to treat AAV
 13 was “*limited*.” Ex. 62 at 534; DX19 at 599. None of Defendants’ exhibits quantified the patients
 14 in the “avacopan” arm receiving non-study steroids *to treat AAV*.¹⁷ Nor were investors told before
 15 May 4-6, 2021 that there was no meaningful difference between the two study arms for steroid use
 16 to treat AAV or that patients treated with steroids *for AAV* were still counted as “responders.”¹⁸

17 Defendants’ analyst testimony does not help them. One of their chosen analysts testified
 18 that he believed, after the mandatory four-week steroid taper, the avacopan arm “got to zero
 19 steroid.” Ex. 179 at 51:2-18, 86:7-87:4, 220:20-221:19. Another testified that he believed that the
 20 avacopan arm was treated “without corticosteroids.” Ex. 166 at 335:8-336:6. And none of them
 21 testified that they knew that 64% of patients in the avacopan arm of ADVOCATE received steroid
 22 to treat AAV or that patients who received steroids to treat AAV were still considered
 23 “responders.” Exs. 166 at 326:9-327:8; 167 at 287:17-290:12; 168 at 114:12-17, 131:22-132-2,
 24 137:17-22, 146:18-22, 203:24-205:7.¹⁹

25
 26 ¹⁷ The *NEJM* figures (S6-S7) and tables (S5-S6) combined all steroid use; none broke out steroids
 27 used to treat AAV. DX 19 at 22-23, 29-33; *see* DX 30 at 11; DX 31 at 10; DX 66 at 14 (re-using
 28 *NEJM* figure and referring to “off-protocol” use, not use to treat AAV).

¹⁸ DX 71-72 were published *after* the first corrective disclosure. The pre-May 4 analyst reports
 cited by Defendants (DX 34 at 1; DX 74 at 2) do not refer to steroid use to treat AAV.

¹⁹ It is irrelevant and of no moment whether an employee at Plaintiff’s investment manager may

Nor did Defendants ever once tell investors that they did not provide standard of care to two-thirds of the patients in ADVOCATE—let alone, that they did so *in order to* manufacture a “superiority” claim. As Defendants internally recognized, “maintenance RTX would *largely abolish* relapses in this trial,” which would make it impossible to show that avacopan was “superior” to “standard-of-care.” Exs. 87-91; 163 at 254:12-257:13. Additionally, Defendants never told investors—in the *NEJM* article or anywhere else—that when only the *actual* standard-of-care patients were considered, “superiority” was no longer statistically significant. Ex. 84.²⁰

Third, Defendants’ “truth on the market” arguments ignore the legal standard. At summary judgment, Defendants have a “heavy burden of proof” to show the truth was “transmitted to the public with a degree of intensity and credibility sufficient to effectively counterbalance any misleading impression.” *Provenz*, 102 F.3d at 1492-93. Accordingly, even if the truth were contained in an appendix to the *NEJM* article or elsewhere (and it was not), there would *still* be a genuine dispute as to whether the “intensity and credibility” of the disclosure was sufficient.²¹

Finally, Defendants’ assertion that they did not know the truth about steroid use in the ADVOCATE trial (Mot. at 27, 29) is not relevant to the truth-on-the-market defense—or even to scienter (addressed *supra* § IV.C), for which the standard is met by showing severe recklessness. In any event, Defendants “meticulously captured” non-study steroid treatment data including the “reason for taking” and calculated the very “64% statistic” long before the FDA’s Briefing Book. Ex. 95 at -154; *see also* Exs. 48; 92-93; 163 at 313:16-21; 165 at 226:8-228:4. Plus, the FDA and the DMC *both* told Defendants for years that the “avacopan” patients received steroids *to treat*

have felt misled (Mot. at 7), as he had no basis to know the truth: he conducted no investigation into the misstatements and did not have access or review non-public information—including FDA minutes, DMC records, or internal ChemoCentryx documents. *See* Ex. 183 at 322:6-324:10, 328:3-329:5, 338:21-340:18, 347:15-348:16, 351:10-352:16, 357:18-359:4, 372:21-373:22.

²⁰ While the *NEJM* article says “no rituximab was given beyond the first 4 weeks,” DX 17 at 601, it does not disclose, among other things, that Defendants knew the patients were *not* given standard of care and they deviated from standard of care *in order* to show “superiority.” Exs. 81-91

²¹ Defendants’ cited cases (Mot. at 26) do not support their defense. *Grigsby* holds plaintiff does “not” have the burden of disproving prior disclosure. 979 F.3d at 1206. *In re Convergent Techs. Sec. Litig.*, 948 F.2d 507, 513 (9th Cir. 1991), involved “more than 60 analyst reports and articles.” *In re Apple Comput. Sec. Litig.*, 886 F.2d 1109, 1116 (9th Cir. 1989), involved “[a]t least twenty articles.” *In re Kalobios Pharms., Inc. Sec. Litig.*, 258 F. Supp. 3d 999 (N.D. Cal. 2017), involved well-publicized reputation of a public figure. *Dalberth v. Xerox Corp.*, 766 F.3d 172, 176-81, 185-88 (2d Cir. 2014), held that Xerox had already disclosed the truth.

AAV, which meant their “low BVAS scores...could be due to steroids.” *See, e.g.*, Exs. 92; 94. Defendants also knew that they purposefully designed ADVOCATE to *undertreat* patients in the “standard-of-care” arm—by *not* providing them the *actual* standard of care, which always includes maintenance therapy—because otherwise there would be too few relapses to show “superiority.” Exs. 81-82; 88; 86. Finally, Defendants also knew, but did not tell investors, about the FDA’s concerns that their undertreatment of patients in the “standard-of-care” arm threatened to “confound the results and bias the assessment of efficacy at Week 52.” Ex. 70.

D. Defendants’ Misstatements And Omissions Are Not Protected By The PSLRA Safe Harbor And Are Not Mere Puffery

In their Motion, Defendants also repeat the same “safe harbor” and “puffery” arguments that the Court has already considered and rejected. MTD Order at 28-29. Their attempt fails again.

First, their statements were not forward-looking: they “highlight[ed] evidence from the [ADVOCATE] trial that was available to Defendants *at the time the statements were made*” and, thus, these statements are “outside the safe harbor.” MTD Order at 28-29 (“[A] defendant may not transform non-forward-looking statements into forward-looking statements that are protected by the safe harbor provisions of the PSLRA by combining non-forward-looking statements about past or current facts with forward-looking statements”); *see also In re Twitter, Inc. Sec. Litig.*, 2021 WL 4166725, at *2 (N.D. Cal. 2021) (*citing In re Quality Sys., Inc. Sec. Litig.*, 865 F.3d 1130, 1142 (9th Cir. 2017)). Statements 55 and 57, which Defendants contend the Court did not previously consider, also include historic data from the trial and are not forward looking. AC ¶310 (ADVOCATE “demonstrated avacopan’s statistical superiority in sustaining remission at 52 weeks over the prednisone-containing standard of care”); ¶312 (same).²²

Second, even if the challenged statements were entirely forward looking (and they are not), they do not qualify for safe-harbor protection because none were accompanied by “meaningful”

²² *Wochos v. Tesla, Inc.*, 985 F.3d 1180 (9th Cir. 2021) involved “unadorned” statements that company was “on track” to meet an objective as opposed to “concrete factual assertion[s] about a specific present or past circumstance” that are “not forward-looking,” even when stated as the “reason why” a future plan “is achievable.” *Id.* at 1192; *see also Twitter*, 2021 WL 4166725, at *3 (distinguishing *Wochos*, and finding statements were not forward looking where, as here, the statements involved “something concrete that had already happened”).

cautionary language that was “precise and directly address[ed]” the alleged misstatements. *In re BioMarin Pharm. Inc. Sec. Litig.*, 2022 WL 597037, at *4 (N.D. Cal. Feb. 28, 2022) (“To be ‘meaningful,’ a cautionary statement must discredit the alleged misrepresentations to such an extent that the ‘risk of real deception drops to nil.’”). Defendants’ generic warnings that the FDA *may* disagree with an interpretation (Mot. at 30) are exactly the kinds of boilerplate warnings that courts routinely reject as insufficient to qualify for the safe harbor. *BioMarin*, 2022 WL 164299, at *8 (warnings that FDA may “delay or prevent approval and commercialization” insufficient); *Chiasma*, 2018 WL 935418, at *4 (warning “that the FDA might disagree with the design or conduct of its clinical trials” insufficient); *In re MannKind Sec. Actions*, 835 F. Supp. 2d 797, 817 (C.D. Cal. 2011) (“[B]oilerplate language concerning the risks inherent in [NDA review] process ... do not address misstatements concerning their past communications with the FDA.”).²³

Additionally, Defendants cannot qualify for safe-harbor protection because—as the evidence shows—they made their misstatements with “actual knowledge.” *See In re JDS Uniphase Corp. Sec. Litig.*, 2007 WL 9751951, at *2 (N.D. Cal. Sept. 14, 2007) (denying summary judgment, while recognizing the “actual knowledge” requirement for forward-looking statements, because “it remains that summary judgment is rarely appropriate with respect to scienter”).

Equally baseless is Defendants’ argument that certain of their misstatements are corporate “puffery”—i.e., immaterial fluff. Mot. at 30. Whether a statement is “puffery” entails “fact-intensive assessments that are more properly left to the jury.” *Mulligan v. Impax Lab’ys., Inc.*, 36 F. Supp. 3d 942, 966 (N.D. Cal. 2014). The Court has already rejected Defendants’ identical “puffery” argument, explaining that Defendants’ statements were accompanied by “concrete facts” that “provide concrete descriptions of the past and present in the form of factual statements about trial results.” MTD Order at 27; *see BioMarin*, 2022 WL 164299, at *12 (statements not “empty opinions similar to puffery” where “they were undergirded by factual assertions”). For example, Statement No. 4 was accompanied by the false concrete claim that avacopan was “superior to the traditional approach of broad immune suppression therapy.” Likewise, Statement No. 28 was

²³ Unlike here, *Police Ret. Sys. of St. Louis v. Intuitive Surgical, Inc.*, 759 F.3d 1051, 1059 (9th Cir. 2014) involved “classic growth and revenue projections, which are forward-looking on their face,” and thus warnings about “future financial performance and guidance” were sufficient. *Id.*

1 accompanied by the false concrete claim that “the ADVOCATE trial provide[d] evidence that
 2 steroids need not be used when avacopan is available.” The same goes for Statement Nos. 31, 34,
 3 105, 110, and 112, which include concrete facts about the trial results, which are not puffery.

4 **E. ChemoCentryx’s After-Market-Hours November 25, 2019 Press Release Is**
 5 **Not An “Inactionable Pre-Class Period” Statement**

6 In a single paragraph in their motion, Defendants urge the Court to summarily dismiss all
 7 misstatements in the November 25, 2019 ADVOCATE Press Release because they are supposedly
 8 “pre-class period statements.” Mot. at 31. Tellingly, Defendants did not make this argument in
 9 moving to dismiss the Complaint or in opposing class certification. There is little wonder why.

10 *First*, Defendants’ misstatements on November 25, 2019 *are* Class Period statements. They
 11 were made *after* the market closed on November 25, 2019 and, accordingly, had no impact on
 12 investors until the next trading day—i.e., November 26, 2019.²⁴ They are identified in the
 13 Complaint as “class period misstatements,” and the Court recognized them as such in its Class
 14 Certification Order. *See* AC ¶¶217-26; CC Order at 2 (“At the start of the Class Period, Defendants
 15 announced the results of a study called ADVOCATE....”).

16 *Second*, courts have rejected Defendants’ precise argument, including Judge George
 17 Herbert King of the Central District of California, who explained:

18 Defendants seek to exclude three of the alleged misrepresentations on the ground
 19 that they were made before the class period. We decline to strike these allegations.
 20 *The two January 25 statements occurred after the close of the market..., and*
 21 *thus had no effect when made. The allegedly fraudulent information was*
 22 *revealed to the market on January 26, the first day of the class period....* We
 23 decline defendants’ invitation to find these statements are non-actionable.

24 *Cherednichenko v. Quarterdeck Corp.*, 1997 WL 809750, at *1 n.1 (C.D. Cal. Nov. 26, 1997).

25 Defendants have not identified a single case from this Circuit disposing of an after-market-
 26 hours misstatement on these grounds, and courts regularly sustain them. *See Shenwick v. Twitter*
 27 *Inc.*, 282 F. Supp. 3d 1115, 1127 (N.D. Cal. 2017) (sustaining after-market-hours statement on
 28 February 5, 2015, when class period began on February 6); *see also In re Twitter Inc. Sec. Litig.*,

24 *See* Exs. 6; 145. Defendants and their expert have admitted as much. *See* ECF No. 87 at 8 (admitting November 25, 2019 misstatements were “after market hours”); Ex. 146 at ¶42 n.51 (“For disclosures made after market hours or on non-trading days, I use ChemoCentryx’s return on the first trading day following the disclosure date in my event study analysis.”).

No. 4:16-cv-05314, ECF No. 102 (letter brief addressing this timing issue); *In re Twitter Inc. Sec. Litig.*, 326 F.R.D. 619, 631 (N.D. Cal. 2018) (certifying class beginning on February 6, 2015); *see also Azar v. Yelp, Inc.*, 2018 WL 6182756 at *2 (N.D. Cal. Nov. 27, 2018) (sustaining after-market-hours statement on February 9, 2017, when the class period began the next day); *In re OmniVision Techs., Inc. Sec. Litig.*, 937 F. Supp. 2d 1090, 1095 (N.D. Cal. 2013) (sustaining statement “after the market closed on August 26, 2010,” when the class period began the next day).

In fact, courts **require** plaintiffs to start class periods on the day following an after-market-hours misrepresentation, as the class period would otherwise include investors who purchased **before** any misrepresentations and, thus, have no injury, standing, or claim. *See, e.g., Sjunde AP-Fonden v. Gen. Elec. Co.*, 341 F.R.D. 542, 549 (S.D.N.Y. 2022) (“[T]he Class Period shall begin on February 29, 2016, the first trading day after GE’s Form 10-K for 2015 was filed.”); *In re Gilat Satellite Networks, Ltd.*, 2007 WL 1191048, at *5 n.15 (E.D.N.Y. Apr. 19, 2007) (ordering the parties to change the class period start date “from February 9 to February 10” because of the “timing of the [after-market-hours misstatement] and the beginning of the Class Period”).

None of Defendants’ cited authorities involve the situation here. In fact, the district court in the lead case cited by Defendants specifically noted this distinction—in that case, plaintiffs did **not** allege the first false “statement was made after the close of the market” and, thus, “waived th[e] contention” that it “might be included in the class period.” *In re Int’l Bus. Machines Corp. Sec. Litig.*, 954 F. Supp. 81, 84 n.5 (S.D.N.Y. 1997).

Third, even if Defendants’ after-market-hours statements on November 25, 2019 could be characterized as “pre-class period statements” (and they cannot be), they would **still** be actionable. As Judge Schwarzer explained in *Zelman v. JDS Uniphase Corp.*, 376 F. Supp. 2d 956 (N.D. Cal. 2005), there is no *per se* rule barring investors from pursuing claims based on pre-class period misstatements. *Id.* at 966 (“The Court rejects the argument that Plaintiff cannot maintain an action on the basis of statements made before the proposed class period.”). This is because the “class period dates function only to define the plaintiff class, **not** to restrict the universe of relevant or actionable facts in this case.” *Id.* at 970. And “the fact that the proposed class period begins after the first of the alleged misstatements does **not** make those earlier statements irrelevant or not

actionable.” *Id.* at 966; *see also Robb v. Fitbit Inc.*, 216 F. Supp. 3d 1017, 1028 (N.D. Cal. 2016) (sustaining misstatements made “both before *and* after the IPO” at the start of the Class Period).

Notably, Defendants’ proposed *per se* rule, if adopted, would lead to absurd results and create a significant loophole in our securities laws. In cases involving after-market-hours misrepresentations, investors would be required to plead over-length class periods that include a day in which no member of the class suffered injury. And when Defendants prevail in shortening the class period to account for this fact, Defendants would then be entitled to dismiss the misstatement as a “pre-class period” misstatement. This approach makes no sense.

Finally, Defendants have been on notice that Plaintiff challenges the ADVOCATE Press Release for over three years. AC ¶¶217-26. In the event the Court finds Defendants’ argument has not been waived and is persuasive, the remedy is not to dispose of the November 25 misrepresentations. Rather, the remedy would be to modify the class definition to even further confirm that it does not somehow exclude misrepresentations made after-trading-hours on November 25, 2019. *Twitter*, 326 F.R.D. at 625 (“[T]he Court retains the power to modify the class definition at a later stage in the proceedings.”).

F. Dr. Cain’s Opinions Do Not “Foreclose” Any Claims

Dr. Cain’s opinions do not “foreclose” the fact that Defendants failed to disclose the FDA’s concerns included in their 2020 communications. Mot. at 31-32. Defendants’ contrary argument is based on a fiction that Plaintiff is required to prove that the inflation in ChemoCentryx’s stock price “increased” following the 2020 FDA Communications. Mot. at 32. But as this Court and others have explained, a reasonable jury may find loss causation under a price-maintenance theory. *Daubert* Order at 32-33; *see also Hatamian v. Advanced Micro Devices, Inc.*, 2016 WL 1042502, at *7 (N.D. Cal. Mar. 16, 2016). None of Defendants’ cited cases holds otherwise.²⁵ The price-

²⁵ In *Smilovits v. First Solar, Inc.*, 2019 WL 7282026, at *6 (D. Ariz. Dec. 27, 2019) (Mot. at 32), the court denied defendants’ *Daubert* motion directed at plaintiff’s expert’s constant-dollar inflation model. The court held that the objection that inflation should increase, rather than be held constant, goes to the weight of the expert’s testimony. *In re Nuvelo, Inc., Sec. Litig.*, 2008 WL 5114325 (N.D. Cal. Dec. 4, 2008) (Mot. at 32), involved a class period that began 13 months after a clinical trial. *Id.* at *4. The court held that plaintiffs’ “unwillingness to extend the class period [earlier] is tantamount to a concession” and thus imposed a special requirement that plaintiffs “allege that defendants only became aware of the undisclosed risks” on the first day of the class

1 maintenance theory is particularly apt here because the FDA, in its 2020 communications, repeated
 2 significant concerns about ADVOCATE that had been previously identified for years, including:
 3 that a lack of maintenance therapy “confound[ed] the results and bias the assessment”; that
 4 ADVOCATE did not support claims that avacopan could be “used alone”; and that ADVOCATE’s
 5 secondary endpoints were not clinically meaningful. *See* Exs. 66-67; 70. Defendants’ argument, at
 6 most, presents a subject area to cross-examine Dr. Cain—not grounds for summary judgment.

7 **G. Plaintiff Has Not “Disclaimed” Any Of Its Theories of Liability**

8 Contrary to Defendants’ suggestion (Mot. 32-33), Plaintiff has never asserted that
 9 Defendants’ statements were false or misleading *because* ChemoCentryx ultimately received—
 10 after the Class Period—approval of a limited label for TAVNEOS. Rather, Plaintiff has always
 11 maintained, and continues to maintain, that Defendants misled investors about the design and
 12 results of ADVOCATE, as well as their communications with the FDA, which cast significant
 13 doubt on ChemoCentryx’s ability to obtain approval for the label it sought—including because the
 14 FDA told ChemoCentryx as early as 2016 that “none of the secondary endpoints are acceptable
 15 from a Regulatory or labeling perspective.” Ex. 77; AC ¶¶88-91. Consistent with Plaintiff’s
 16 position throughout, Lead Counsel reiterated at the *Daubert* hearing that post-Class Period
 17 events—including the ultimate TAVNEOS approved label—are not relevant and, if allowed into
 18 evidence, would confuse the jury. Ex. 159.

19 Plaintiff’s counsel did not “disclaim” any theories of liability at the *Daubert* hearing.
 20 Rather, Lead Counsel reiterated what was in its *Daubert* briefs: that Plaintiff does “not intend to
 21 introduce evidence about post-class period events at trial [including evidence about the TAVNEOS
 22 label] so long as Defendants are equally restricted.” Ex. 159 at 27:12-14; *compare Williams v. City*
 23 *of Las Vegas*, 359 Fed. App’x 753, 754 (9th Cir. 2009) (plaintiff “abandoned” claims at oral
 24 argument). Lead Counsel’s statements were made in the context of the Court’s tentative ruling that
 25 it was “unlikely to allow post-class period evidence of FDA approval.” Ex. 159 at 4:11-12. If the
 26

27
 28

 period. *Id.* at *5-6. That rule is not implicated here. *Nuvelo* says a class period can begin when
 defendants make “affirmative statements” that “ma[k]e the omission of the risks misleading for
 the first time,” (*id.* at *6)—which a jury could find to be true here if required. *Nuvelo* did not
 discuss price maintenance or hold that a misstatement must increase inflation to be actionable.

1 Court ultimately admits evidence of the FDA’s “approval” of TAVNEOS—an evidentiary ruling
 2 the Court deferred—Plaintiff will, of course, require the ability to rebut that evidence by presenting
 3 to the jury the limitations of the FDA’s “approval.”

4 **H. Previously Dismissed Statements**

5 The Parties agree that the Court previously dismissed the misstatement at AC ¶¶367 (MTD
 6 Order at 17) and portions of misstatements at AC ¶¶251, 253, 255, 271, 282, 330, 374, and 420,
 7 which state that ChemoCentryx submitted an NDA based on ADVOCATE’s results (MTD Order
 8 at 19). The other portions of misstatements at AC ¶¶251, 253, 255, 271, 282, 330, 374, and 420,
 9 were not previously dismissed by the Court and are actionable.

10 **I. Plaintiff’s Section 20A And 20(a) Claims Are Valid**

11 Defendants do not raise separate grounds for summary judgment on Plaintiff’s Section 20A
 12 and 20(a) claims. Mot. at 32. For the reasons above, Defendants’ challenge fails.

13 **VI. PLAINTIFF IS ENTITLED TO PARTIAL SUMMARY JUDGMENT**

14 Plaintiff filed a narrow motion for partial summary judgment. Defendants do not identify
 15 any material, factual disputes. The Court does not need to decide when “the ‘truth’ was ‘revealed’”
 16 to resolve the motion, as the cases cited by Plaintiff (and ignored by Defendants) make clear. *See*
 17 ECF No. 267 at 2 (citing cases granting identical partial motions for summary judgment). And
 18 Plaintiff’s case does not “rest on market inefficiencies.” The Ninth Circuit has repeatedly held that,
 19 in an efficient market, technical and complex information may take time, multiple disclosures, and
 20 expert analysis to fully digest. *Bofi*, 977 F.3d at 791-95. Tellingly, in ignoring that controlling law,
 21 Defendants cite *Meyer v. Greene*, 710 F.3d 1189 (11th Cir. 2013), whose “bright-line rule” the
 22 Ninth Circuit has expressly rejected. *Bofi*, 997 F.3d at 795 & n.5.²⁶

23 **VII. CONCLUSION**

24 For these reasons, Defendants’ motion for summary should be denied, and Plaintiff’s
 25 narrow motion for partial summary judgment should be granted.

26
 27 ²⁶ Defendants also cite decisions that *pre*-date the Ninth Circuit’s decisions in *Bofi* and *Genius*
 28 *Brands*, and follow *Meyer*, which the Ninth Circuit rejected. *See* Mot. at 34 (citing *Bonanno* and
Mandalevy). They also cite *Mandalevy*, which was reversed in relevant part *sub nom.* *Grigsby*, 979
 F.3d at 1206-08. Lastly, they cite *Bricklayers*, which is distinguishable because (among other
 things) plaintiff’s loss causation expert was excluded.

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